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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/804,093	03/12/2001	Robert Scott	6511-C1-11-EJF	7994

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EXAMINER

SHEIKH, HUMERA N

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 08/22/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/804,093

Applicant(s)

SCOTT ET AL.

Examiner

Humera N Sheikh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2002 (paper no.8).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34,41,54-57 and 60-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34,41,54-57 and 60-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION
Status of the Application

Acknowledgement is made of the receipt of the Election of species with traverse filed 06/04/02.

Claims 34, 41, 54-57 and 60-62 are pending. Claims 34, 41, 54-57 and 60-62 are rejected.

Applicant's arguments filed 06/04/02 have been fully considered but they are not persuasive. The applicants have not placed on record that the species set forth are obvious variants.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 34, 41 and 54-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hansen *et al.* (US Pat. No. 6, 423,346 B1).

Hansen *et al.* teach a fish gelatinous composition containing at least 50% (and more preferably at least 70% and at least 90%) by weight of fish gelatin, water (0-10%) and a hydrocolloid system comprising various polysaccharides such as gum arabic, tragacanth gum, karaya gum, ghatti gum, agar gum, alginates, guar gum, carrageenan, starches and celluloses (see reference column 2); (col. 3, lines 43-67); (col. 5) and examples.

Hansen *et al.* while teaching a fish gelatinous composition containing at least 50% by weight of fish gelatin, 0-10% water and a hydrocolloid system, do not explicitly teach the specifically claimed amount of the hydrocolloids. It would have been obvious to one of ordinary skill in the art at the time the invention was made that suitable amounts of a hydrocolloid could be determined through routine or manipulative experimentation. The expected result would be a fish gelatinous composition wherein the hydrocolloid would function as a protective agent aid in increasing the mechanical strength, improve storage stability, reduce degradation of the active ingredient and act as an emulsifier.

Hanes *et al.* teach a fish gelatinous composition in the form of a tablet or microcapsule. Hanes *et al.* do not teach a gelatinous composition in the form of a

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capsule, wherein the capsule is made by dipping a forming mold into a gelatinous solution.

Claims 60-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones (US Pat. No. 4, 892,766).

Jones teaches two-piece hard gelatin capsules comprising water (about 13%-16%) and polysaccharides in an amount up to about 10%, wherein the capsules can be made by dipping mould pins into a hot solution of gelatin (or by incorporating the fibrous materials into an aqueous suspension of molten gelatin), removing the pins from the gelatin solution, allowing the gelatin to set by drying and stripping the shells from the pins (see reference columns 1 and 2).

Therefore, it would have been obvious to one of ordinary skill in the pharmaceutical art at the time the invention was made to formulate a two-piece hard gelatin capsule made by dipping a capsule into a forming mold with an aqueous gelatin solution because it could help overcome problems of embrittlement and splitting of the capsule walls after storage. The expected result would be an improved hard gelatin capsule resistant to embrittlement, cracked or split capsules and thus enhanced storage capabilities.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

0091 THURMAN PAGE
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HUMERA SHEIKH
EXAMINER